REMARKS

Claims 58, 61-63, 65-68, 70, 73, 76-77, 81-82, 84, 86-87, 90, 92, 95, 98-112, 114, 116-119, 121-123, 125, 126, 128-131, 133, 134, 136-139, 141-143 are currently pending in this application. No claims have been amended. Claims 58, 62, 63, 66-68, 70, 73, 76, 77, 84, 86, 92, 95, 98-106, 111, 112, 116-119, 121, 123, 125, 126, 128-131, 133, 134, 136-139, 141 and 142 have been have been withdrawn from consideration as being drawn to non-elected species. Upon notice of an allowable generic claim, Applicant reserves the right to rejoin the withdrawn subject matter. No new matter has been added.

Rejection under 35 USC §102(b)

Claims 61, 65, 81-82, 87, 90, 107-110, 114, 122 and 143 remain rejected under 35 USC §102(b) as being anticipated by US Patent No. 4,814,182 to Graham ("Graham"). Specifically, the Examiner indicates that Graham discloses the formation of a polyethylene oxide hydrogel by reacting polyethylene oxide, hexane triol and bis isocyanatocyclohexyl, and antifungal agents that are dispersed in the polymerizing monomers or hydrogel and therefore Graham meets the limitations of the claims. (*See*, Office Action at page 2). Applicants respectfully disagree.

In order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). Claims 87, 107-110, 114, 122 and 143, from which the remaining claims depend, in a first step, require a biologically active agent be dispersed or dissolved in one or more carrier starting substances to a first degree of saturation. The claims then require, in a second step, that the starting carrier starting substances be subjected to a chemical reaction to produce a liquid or solid non-crystalline carrier matrix, where the biologically active agent is dissolved or dispersed to a second degree of saturation, and where the second degree of saturation is more than the first degree of saturation.

The Examiner argued that saturated state of the claimed composition is formed/obtained when the carrier composition containing the active agent is "subjected to chemical operations" and because the active agent of Graham is "incorporated therewith," into hydrogel and the hydrogel is formed by cross-linking/polymerization reaction of monomers, the active agent is incorporated therewith is inherently in the saturated state. (*See*, Office

Action at page 3). Further the Examiner stated that since the active agent of Graham is incorporated therewith in the hydrogel, the active agent is already present in the hydrogel in the casting or molding stage. (See, Office Action at page 3).

However, Applicants submit that Graham does not teach that an active agent is incorporated therewith in a hydrogel, wherein the active agent is already present in the hydrogel in the casting or molding stage. In examples 1-4 of Graham, two polyethylene oxide hydrogels were prepared using the same ingredients but at different ratios, the second hydrogel was cast as a hollow cylinder and the first was cast as a plug mating the hollow cylinder. (*See*, Graham at column 7, lines 47-60). At this point, each of the hydrogels have been formed by cross-linking/polymerization reaction of monomers, and neither have the active ingredient incorporated therewith. (*See*, Graham at column 7, lines 47-60).

The active ingredient is added to the cavity produced by the machining of the internal groove of the cylinder cast, *i.e.* after the cast has hardened, and the plug is then placed into the cavity. (*See*, Graham at column 7, lines 55-60). No incorporation or dispersion of the active agent occurs at this time. (*See*, Graham at column 7, lines 55-60). The complete hydrogel cast containing the active ingredient crystals is then placed into a swollen silicon rubber tube which is sealed around the hydrogel cast. (*See*, Graham at column 7, line 63 through column 8, line 15). At no time was the active-ingredient, incorporated therein or dispersed throughout the hydrogel, *i.e.* no chemical reaction occurs as required by the claimed invention. (*See*, Graham at column 7, line 63 through column 8, line 15).

The Examiner also argued that Graham discloses that "the active substance may be homogeneously or in-homogeneously dispersed throughout the hydrogel" and/or "may also be contained in a reservoir within the hydrogel." (*See*, Office Action at page 4). However, Applicants submit that Graham does not teach a method of dispersing an active substance through a gel according to the methods of the instant claims.

In examples 5- 11 of Graham, the hydrogel casts were made as described above, without any active ingredient, but molded into a cuboid, and upon hardening, the cuboid was cut into slabs. (*See*, Graham at column 9, lines 17-28). The hardened slabs were then swollen in a solution containing the active ingredient until equilibrium (not a supersaturated state) is

obtained and then were allowed to dry, at which point the dried slabs were coated with a water-impermeable coating. (*See*, Graham at column 9, lines 28-38). During the swelling, no chemical reaction is taking place as required by the instant claims, rather the active ingredient is merely diffusing between the solution and hydrogel cast in order to reach an equilibrium state.

In contrast to both types of examples in Graham discussed above, the present invention requires that a biologically active agent is dissolved or dispersed to a first degree of saturation in the one or more carrier starting substances, *i.e.* the active ingredient is initially incorporated in the composition. The carrier starting substances, which contains the active ingredient, are subjected to a chemical reaction over a period of time to form a liquid or a solid non-crystalline carrier matrix in which the biologically active agent is present at a second degree of saturation that is higher than that of the initial mixture so as to form the biologically active composition.

As articulated above, there is no teaching in Graham that the hydrogels are created or molded where the active ingredient is present. Moreover, there is no teaching in Graham that the carrier starting substances are involved in a chemical reaction in the presence of the active ingredient, let alone a polymerization reaction. As such, Graham does not teach each and every limitation of claims 61, 65, 81-82, 87, 90, 107-110, 114, 122 and 143 and cannot anticipate them.

Reconsideration and withdrawal of the rejection is requested. Applicants respectfully submit that the application is now in condition for allowance.

Conclusion

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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